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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/574,852 | 10/19/2006 | Ivan Petyaev | BJS-620-433 | 8419 |
| 23117 | 7590 | 10/08/2008 | EXAMINER | |
| NIXON & VANDERHYE, PC | | | PESELEV, ELLI | |
| 901 NORTH GLEBE ROAD, 11TH FLOOR | | | ART UNIT | PAPER NUMBER |
| ARLINGTON, VA 22203 | | | 1623 | |
| MAIL DATE | | DELIVERY MODE | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|
| Office Action Summary | Application No. 10/574,852 | Applicant(s) PETYAEV, IVAN |
| | Examiner Elli Peselev | Art Unit 1623 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on **24 July 2008**.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) **12-14, 16-22, 27 and 29-32** is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) **12-14, 16-22, 27 and 29-32** is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/06)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-14, 16-22, 27 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petyaev (WO 03/017992) in view of Shiff et al (U.S. Patent No. 6,201,028).

Petyaev discloses the treatment of atherosclerosis with a combination of azithromycin and a metal chelator such as aspirin (page 10) but does not disclose the treatment of hyperlipidemia. However, since atherosclerosis is associated with hyperlipidemia as disclosed by Shiff et al (columns 1-2 and column 8, lines 16-23), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to use the composition disclosed by Petyaev for the treatment of hyperlipidemia.

Applicant's arguments filed July 24, 2008 have been fully considered but they are not persuasive.

Applicant contends that Shiff et al do not teach correlation between atherosclerosis and hyperlipidemia. This argument has not been found persuasive since Shiff et al disclose in column 8, lines 14-23 that aspirin also unexpectedly reduced the level of cholesterol and thus is "useful for the prevention and treatment of hyperlipidemia and atherosclerosis.

Applicant also contends that Shiff et al does not contain any teaching which would suggest to the ordinary skilled person that the Petyaev compositions would have any effect on hyperlipidemia. This argument has not been found persuasive since Shiff et al disclose that aspirin is useful for treating hyperlipidemia and the composition disclosed by Petyaev contains aspirin. Therefore, the composition disclosed by Petyaev would have been expected by a person having ordinary skill in the art to have an effect on hyperlipidemia.

Claims 12-14, 16-22, 27 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (U.S. Patent No. 6,174,865) in combination with Shiff et al (U.S. Patent No. 6,201,028).

Klein discloses the treatment of hyperlipidemia with a macrolide antibiotic such as aspirin (column 2, lines 13-20). Shiff et al disclose the use of acetylsalicyclic acid (aspirin) for the treatment of hyperlipidemia (coumn 8, lines 16-23). Therefore, it would have been *prima facie* obvious to a person having ordinary skill in the art at the time the claimed invention was made to use a combination of a macrolide antibiotic with aspirin for the treatment of hyperlipidemia because the results from such a combination would have been expected.

Applicant's arguments filed July 24, 2008 have been fully considered but they are not persuasive.

Applicant contends that Shiff et al do not disclose correlation between atherosclerosis and hyperlipidemia. This argument has not been found persuasive since Shiff et al disclose in column 8, lines q4-23 that aspirin unexpectedly reduced the

level of cholesterol and thus is "useful for the prevention and treatment of hyperlipidemia and atherosclerosis". Further, Klein discloses the use of macrolides, including azithromycin, for the treatment of hypertriglyceridemia. Therefore, the claimed methods directed to the use of composition containing macrolides, would be expected to be useful for treating hypertriglyceridemia.

The data presented on pages 11-13 and Table 3 of the specification has been considered but has not been found persuasive. On page 13 of the specification it is stated that the most significant effect on the serum parameters of lipid metabolism was observed in Group B. As stated on page 12 of the specification Group B received 500mg of azithromycin and 250 mgs daily. None of the claims have been limited to the composition tested. Therefore, it cannot be ascertained which specific combinations of which compounds and what amounts encompassed by the present claims will produce similar effects. The scope of the claimed invention is not commensurate with the data set forth in the specification.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623